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TITLE: Apparatus and methods for dilating
vessels and hollow-body organs

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Abstract Text - ABTX (1):

Apparatus and methods for dilating a vessel or organ, especially a larger diameter vessel or organ, are provided using a catheter having a balloon element is disposed within a sheath having an expandable but non-compliant mesh region covering the balloon element. The sheath is selected from among a plurality of sheaths each having a mesh member that is expandable to a different predetermined expanded diameter, the mesh region preventing the balloon member from developing bulges during inflation and constraining the edges of the balloon from perforating the vessel in the event of perforation. The sheath, which extends to a proximal end of the catheter, is also employed to reduce the diameter of the balloon member following the dilatation procedure, thereby preventing the balloon from bunching up in the vessel or organ.

Brief Summary Text - BSTX (7):

Balloon dilatation devices generally employ either minimally-compliant balloons, which experience a relatively small increase in diameter when the balloon is expanded, or compliant balloons, which experience a relatively large

increase in diameter in response to an increase in pressure, as described, for example, in U.S. Pat. No. 5,447,497 to Sogard et al.

Non-compliant balloons

are generally favored for angioplasty because they may be reliably expanded to a known size, whereas compliant balloons permit treatment over a larger range of diameters. In order to provide a mixture of the desirable characteristics of each of these types of balloons, dilatation devices have been designed, as described in U.S. Pat. No. 5,447,497, that include layers of both compliant and non-compliant material.

Brief Summary Text - BSTX (8):

Other balloon dilatation devices have employed elastomer impregnated braided material or nets to constrain the inflated size of the device, such as described in U.S. Pat. No. 4,702,252 to Brooks et al. and U.S. Pat. No. 4,108,236 to Ochiai et al. Still other devices, such as described in U.S. Pat. No. 4,998,539 to Delsanti and U.S. Pat. No. 5,221,261 to Termin et al. include members for supporting a vessel following angioplasty. U.S. Pat. No. 4,998,539 describes a separately movable plaited net disposed over a balloon catheter. The plaited net is expanded against the interior of the vessel by the balloon during angioplasty, and temporarily remains in place after balloon deflation to prevent detachment of material from the vessel wall.

Brief Summary Text - BSTX (20):

In one preferred embodiment of the apparatus of the present invention, a catheter having a balloon element is disposed within a sheath having an expandable but non-compliant mesh region covering the balloon element. In

accordance with the present invention, the sheath is selected from among a plurality of sheaths each having a mesh member that is expandable to a different predetermined diameter. The expandable mesh region prevents the balloon member from developing bulges during inflation, and constrains the edges of the balloon from dissecting or rupturing the vessel in the event of balloon rupture. The sheath, which extends to a proximal end of the catheter, is also employed to reduce the diameter of the balloon member following the dilatation procedure, thereby preventing the balloon from bunching up in the vessel or organ.

Brief Summary Text - BSTX (21):

In alternative embodiments, a plurality of sheaths having mesh regions of different predetermined expanded diameters may be provided as separate elements designed to be used in conjunction with any previously known balloon catheters, so that a previously known catheter may be modified for use in treating hardened stenoses or larger diameter vessels. Methods of using the apparatus of the present invention to dilate vessels and organs are also provided.

Detailed Description Text - DETX (3):

Referring to FIG. 1, illustrative apparatus 10 constructed in accordance with the present invention is described. Apparatus 10 includes catheter 11 having balloon element 12 and sheath 13 having expandable but non-compliant mesh 14 disposed over balloon element 12. In accordance with the present invention, apparatus 10 may be provided wherein the non-compliant mesh may be selected from among a plurality, in which each non-compliant mesh has a

different predetermined expanded diameter.

Detailed Description Text - DETX (5):

Referring to FIG. 3, sheath 13 is joined in distal end region 30 to

expandable mesh 14. Expandable mesh 14 includes rigid retainer ring 15

disposed from the distal end of expandable mesh 14 that engages distal end 16

of catheter 11. Rigid retainer ring 15 maintains expandable mesh 14 aligned

with balloon member 12, and prevents proximal force on retractor knob 23 from

pulling the expandable mesh to a position proximal to balloon element 12.

Sheath 13 is shorter than catheter 11 so that, when sheath 13 is disposed over catheter 11, retraction of retractor knob 23 in the proximal direction will not interfere with inflation port 22.

Detailed Description Text - DETX (6):

As shown in FIG. 4, expandable mesh 14 contacts the exterior surface of

balloon element 12. Expandable mesh 14 comprises a very low compliance

material, such as a monofilament polyester mesh, or a mesh formed of stainless

steel, Kevlar.RTM. (a fiber produced from

poly-paraphenylene terephthalamide,

sold by E. I. DuPont de Nemours, Wilmington, Del.),

nickel-titanium alloy or

other high strength material, so that the maximum inflated size of the device

is determined by the predetermined expanded diameter of mesh 14. The filaments

of expandable mesh 14 move with respect to one another so that upon inflation

of the balloon element, the mesh 14 expands and pulls sheath 13 and retractor

ring 23 in the distal direction. After balloon element 12 is deflated,

expandable mesh 14 may be returned to its contracted state by pulling proximally on retractor ring 23.

Detailed Description Text - DETX (7):

It is contemplated that use of sheath 13 and expandable mesh 14, in conjunction with previously known balloon catheters, will enable the balloons of those devices to be inflated to twice or more the rated burst pressures, without rupture. For example, applicant has determined that a balloon having a rated pressure of 5 atmosphere may be safely inflated to about 25-30 atm without rupture. In addition, by selection of a desired predetermined expanded diameter of mesh 14, it is expected that balloons of previously known catheters may be inflated to diameters twice or more larger than the rated diameters of those balloons when used with the sheath and expandable mesh of the present invention, again without rupture.

Detailed Description Text - DETX (8):

It is further contemplated that expandable mesh 14 of the present invention imposes a radial and longitudinal stress on the balloon element during inflation that tends to equalize the circumferential and longitudinal stresses developed in the balloon member. This equalization of stresses around the balloon element is expected to reduce the risk of bulging and concomitant localized loss of strength of the balloon element. Moreover, expandable mesh 14 serves to confine the edges of balloon element 12 in those few cases where the balloon does rupture, thereby reducing the risk of dissection of a vessel caused by rupture, and trapping any pieces of the perforated balloon element.

Detailed Description Text - DETX (9):

In a preferred embodiment of the present invention,

catheter 11 and balloon element 12 may comprise materials commonly used in previously known balloon catheters, e.g., polyethylene or PET. Balloon element 12 may also comprise a compliant material, such as nylon. Sheath 13 preferably comprises a material commonly used in catheter construction, such as polyethylene or polyvinylchloride, while expandable mesh 14 preferably comprises a structure woven from polyethylene strands (i.e., monofilament polyester mesh). Alternatively, expandable mesh 14 may comprises strands of another polymer, Kevlar.RTM., stainless steel, nickel-titanium alloy or other high strength material. Preferably, the cross-points of the mesh are not interconnected, so that the strands may slide freely over one another when balloon element 12 is inflated. Sheath 13 and retainer ring 15 may be joined to expandable mesh 14 using any suitable method, such as thermowelding or biocompatible adhesive.

Detailed Description Text - DETX (10):

Operation of apparatus 10 of the present invention is now described for dilating a vessel. Typically, guidewire 40 first is disposed across a stenosis using an introducer catheter, as is well known in the art. Retractor knob 23 of sheath 13 is pulled in the proximal direction to elongate expandable mesh 14, and apparatus 10 is then advanced along guidewire 40 so that balloon element 12 is disposed across the stenotic region under fluoroscopic guidance, as determined, for example, using radio-opaque markers contained within balloon element 12.

Detailed Description Text - DETX (11):

Balloon element 12 is then inflated via lumen 24 and

inflation port 22. In accordance with the methods of the present invention, balloon element 12 is inflated to until constrained by expandable mesh 14, which in turn will expand only to its predetermined expanded diameter, and no further. Balloon element 12 may be expanded to twice or more its rated pressure, or twice or more its rated diameter, without bulging or rupture. As balloon element 12 expands, expandable mesh 14 opens to its predetermined expanded diameter, thereby causing disruption of the stenosis (e.g., compressing or cracking plaque to restore the patency of the vessel or organ).

Detailed Description Text - DETX (12):

Upon completion of the step of dilating the vessel, as determined, for example, by angiography, balloon element 12 is deflated. The clinician then grasps retractor knob 23, and while holding catheter 11 steady using luer 21, pulls retractor knob 23 in the distal direction, thereby contracting expandable mesh 14 to approximately its initial diameter. Apparatus 10 may then be withdrawn proximally from the patient's vessel or organ.

Detailed Description Text - DETX (13):

With respect to FIG. 5, apparatus 50 constructed in accordance with the present invention is described. Apparatus 50 comprises sheath 51, expandable mesh 52, retainer ring 53 and retractor knob 54. Apparatus 50 is constructed as described hereinabove with respect to the similar components of apparatus 10 of FIG. 1, and is intended to be used with commercially available, previously known, balloon catheters. In particular, apparatus 50 is intended to be slipped onto a previously known catheter to provide the same benefits as

apparatus 10 of FIG. 1. Retainer ring 53 is sized so that it engages the distal neck of the balloon element, and thus cannot be pulled too far in the proximal direction (i.e., retainer ring 53 keeps expandable mesh 52 aligned with and disposed over the balloon element).

Detailed Description Text - DETX (15):

Apparatus 60 includes sheath 63 having expandable mesh 64 and retainer ring 65. In accordance with this aspect of the invention, sheath 63 includes an elongate aperture or slit 66 through which guidewire 75 exits sheath 63. In this manner, sheath 63 is free to move distally (upon inflation of balloon element 63) or proximally (when pulled by retractor knob 67), without interfering with guidewire 75.

Claims Text - CLTX (5):

a mesh portion attached to the distal end of the sheath and disposed surrounding the balloon for sliding movement relative thereto, the mesh portion comprising a non-compliant material having a first state wherein the mesh portion has a first length and an insertion diameter and a second state wherein the mesh portion has second length, shorter than the first length, and a selected predetermined expanded diameter; and

Claims Text - CLTX (7):

wherein, when the balloon is fully inflated, the mesh portion is in the second state and attains the selected predetermined expanded diameter, the mesh portion constraining the balloon from further expansion.

Claims Text - CLTX (8):

2. The apparatus as defined in claim 1 wherein the mesh

portion enables the
balloon to be expanded to at least twice a rated burst pressure of the balloon.

Claims Text - CLTX (9):

3. The apparatus as defined in claim 1 wherein the mesh portion enables the balloon to be inflated to at least twice a rated inflation pressure of the balloon.

Claims Text - CLTX (11):

a retainer ring disposed on the distal end of the mesh portion, the retainer ring engaging the catheter at a position distal of a distal neck of the balloon.

Claims Text - CLTX (17):

a sheath selected from among a plurality of sheaths, each one of the plurality of sheaths including a mesh portion having a predetermined expanded diameter, each one of the sheaths comprising:

Claims Text - CLTX (19):

a mesh portion attached to the distal end of the tubular member and disposed surrounding the balloon for sliding movement relative thereto, the mesh portion comprising a non-compliant material having a first state wherein the mesh portion has a first length and an insertion diameter and a second state wherein the mesh portion has second length, shorter than the first length, and a predetermined expanded diameter; and

Claims Text - CLTX (21):

wherein, when the balloon is fully inflated, the mesh portion of the selected one of the plurality of sheaths is in the second

state and attains the predetermined expanded diameter, the mesh portion constraining the balloon from further expansion.

Claims Text - CLTX (22):

9. The kit as defined in claim 8 wherein the mesh portion of at least one of the plurality of sheaths enables the balloon to be expanded to at least twice a rated diameter of the balloon.

Claims Text - CLTX (23):

10. The apparatus as defined in claim 8 wherein the mesh portion of at least one of the plurality of sheaths enables the balloon to be inflated to at least twice a rated inflation pressure of the balloon.

Claims Text - CLTX (25):

a retainer ring disposed on the distal end of the mesh portion, the retainer ring engaging the shaft at a position distal of a distal neck of the balloon.

Claims Text - CLTX (30):

providing apparatus comprising a catheter a distal end and a balloon disposed on the distal end and a sheath disposed on the catheter, the sheath including a mesh portion aligned with and surrounding the balloon, the mesh portion arranged for sliding movement relative to the balloon, the mesh portion comprising a non-compliant material having a first state wherein the mesh portion has a first length and an insertion diameter and a second state wherein the mesh portion has second length, shorter than the first length, and a selected predetermined expanded diameter;

Claims Text - CLTX (33):

advancing the apparatus along the guidewire to position the mesh portion and balloon within the constriction; and

Claims Text - CLTX (34):

inflating the balloon so that the mesh portion expands to the second state and attains the selected predetermined diameter to disrupt the constriction, the mesh portion constraining the balloon from further expansion.

Claims Text - CLTX (45):

inserting the catheter within the sheath so that the mesh portion is aligned with the balloon.